

Serial No. 10/743,373

Dkt.: P-11209.04

Filing Date: December 22, 2003

Title: DISPOSABLE, INTEGRATED EXTRACORPOREAL BLOOD CIRCUIT

**Remarks**

The Office Action objected to claims 29 and 42 based on informalities. The enclosed amendment is believed to render the informalities moot. The Examiner is thanked for the careful review of this application as evidenced by the detection of these informalities.

Claim 25 was a repeat of claim 24 so it is canceled.

The informal original drawings were objected to. Please find enclosed 24 pages of formal replacement drawing sheets. The enclosed formal drawings are believed to fully address the drawing objections.

Claims 18, 19, 21, 22, 27 and 42 are rejected under 35 U.S.C. Section 103(a) as being unpatentable over U.S. Pat. No. 5,540,653 to Schock. Claims 26 and 28 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over U.S. Pat. No. 5,540,653 to Schock in view of U.S. Pat. No. 6,306,346 to Lindsay. Claim 40 was rejected under 35 U.S.C. Section 103(a) as being unpatentable over U.S. Pat. No. 5,540,653 to Schock in view of U.S. Pat. No. 6,824,524 to Favre. Claims 41 and 43 rejected under 35 U.S.C. Section 103(a) as being unpatentable over U.S. Pat. No. 5,540,653 to Schock in view of U.S. Pat. No. 6,607,698 to Spears.

Claims 2-9, 11-17, 20, 23-25 and 29-39 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form. The Examiner is respectfully thanked for the indication of allowable subject matter in this case.

Claim 20 was indicated as including allowable subject matter in the Office Action. It is placed in independent form in this amendment. Please charge the fee for the submission of this additional independent claim to Deposit Account No. 13-2546.

Claims 1 and 10 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28 and 29 of copending Application No. 10/743,357. Applicants respectfully submit that the rejection

Serial No. 10/743,373

Dkt.: P-11209.04

Filing Date: December 22, 2003

Title: DISPOSABLE, INTEGRATED EXTRACORPOREAL BLOOD CIRCUIT

is inappropriate. Neither patent application has been allowed. Moreover, applicants respectfully submit that original claims 1 and 10 are patentably distinct from claims 28 and 29 of copending Application No. 10/743,357. Nonetheless, solely out of a motivation to expedite prosecution of the present application, and not as an admission as to the propriety of the double patenting rejection, applicants supply a terminal disclaimer. This is believed to render the double patenting rejection moot. As a result, claims 1-17 are believed to be in condition for allowance in their original form.

With respect to the rejection of claim 18 based on Schock et al., the Office Action suggests that the only element of claim 18 that is not taught by Schock is that "the filter/trap and blood pump are directly connected." Applicants respectfully disagree.

It is respectfully submitted that the Office Action fails to reasonably compare claim 18 to Schock. Among other elements, claim 18 sets forth a blood pump, a *venous* air removal device and an *arterial* filter. While the Office Action identifies trap/filter 16 of Schock as a venous air removal device and a filter, applicants respectfully submit this is clear error. The Office Action is taking the position that the *same* element can be both a venous air removal device AND an arterial filter at the same time. This is impossible. As a result, the rejection should be withdrawn.

Claim 18 sets forth: a system of a disposable, extracorporeal blood circuit and reusable circuit holder for providing extracorporeal oxygenation of a patient's blood during cardiopulmonary bypass surgery adapted to be performed in the presence of a perfusionist on a patient in an operating room and employing a venous return line and an arterial line coupled to the respective venous and arterial systems of the patient, the system comprising: a blood pump having a blood pump inlet and a blood pump outlet and adapted to be operated to pump venous blood into the blood pump inlet and out of the blood pump outlet; a venous air removal device (VARD) having an upper venous blood inlet coupled to the venous return line and a lower venous blood outlet coupled to the blood pump inlet; a blood oxygenator having an oxygenator venous blood inlet coupled to the blood pump outlet and an oxygenated blood outlet, the blood oxygenator adapted

Serial No. 10/743,373

Dkt.: P-11209.04

Filing Date: December 22, 2003

Title: DISPOSABLE, INTEGRATED EXTRACORPOREAL BLOOD CIRCUIT

to be operated to oxygenate venous blood; an arterial filter having an arterial filter inlet coupled to the oxygenated blood outlet of the blood oxygenator and an arterial filter outlet coupled to the arterial line; a disposable circuit support module supporting and spatially arranging the blood oxygenator, the VARD, the arterial filter, and the blood pump in 3-D space; and a reusable circuit holder having a vertical mast adapted to extend vertically adjacent to the patient, and a support arm assembly extending laterally from the vertical mast engaging and supporting the disposable circuit support module above the floor of the operating room. Schock merely discloses a conventional preassembled bypass circuit. It does not disclose the elements of the present invention and it cannot be fairly said that the invention of claim 18 is obvious in view of it unless one employs impermissible hindsight reconstruction of the invention.

The remaining references cited against the claims in the Office Action do not cure the deficiencies of Schock. Lindsay discloses a self-contained pack assembly for an extracorporeal circuit. Favre discloses tubing for extracorporeal purification of blood. Spears discloses a method of generalized extracorporeal support. None of these references can be combined with Schock to render claim 18 obvious. Thus, it is respectfully submitted that claim 18 and its dependent claims 19-24 and 26-43 are in condition for allowance.

Reconsideration and withdrawal of the rejections of the claims, in view of the remarks and amendments presented herein, is respectfully requested.

A supplemental information disclosure statement and a petition for a two month extension of time accompany this amendment.

Please charge the fee for the supplemental information disclosure statement, the fee for the additional independent claim, the extension of time fee, and the fee of \$130.00 for the terminal disclaimer to Deposit Account No. 13-2546.

If any questions remain in this case, the Examiner is invited to telephone Applicants' attorney at (763) 391-9661 to facilitate prosecution of this application.

AMENDMENT AND RESPONSE

Page 20

Serial No. 10/743,373

Dkt.: P-11209.04

Filing Date: December 22, 2003

Title: DISPOSABLE, INTEGRATED EXTRACORPOREAL BLOOD CIRCUIT

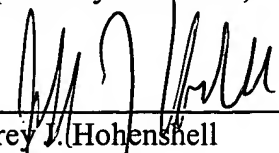
**Conclusion**

Applicants respectfully submit that claims 1-24 and 26-43 are in condition for allowance, and notification to that effect is earnestly requested.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 13-2546.

Date: October 4, 2006

Respectfully submitted,

By 

Jeffrey J. Hohenshell

Reg. No. 34,109

Sr. Patent Counsel

MEDTRONIC, INC.

710 Medtronic Parkway

Minneapolis, MN 55432

Tel. 763.391.9661

Fax. 763.391.9668

Customer No. 27581

**AMENDMENT AND RESPONSE**

**Page 2**

Serial No. 10/743,373

Dkt.: P-11209.04

Filing Date: December 22, 2003

Title: DISPOSABLE, INTEGRATED EXTRACORPOREAL BLOOD CIRCUIT

**In the drawings:**

Please find enclosed formal drawing sheets labeled "Replacement Sheet" for this application.